PUBLIC BRIEF - SEALED MATERIAL DELETED
ORAL ARGUMENT NOT YET SCHEDULED

No. 22-5137

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

FEDERAL TRADE COMMISSION,
Plaintiff-Appellant,

v.

ENDO PHARMACEUTICALS INC., ET AL.,
Defendants-Appellees.

On Appeal from the United States District Court
for the District of Columbia
No. 1:21-cv-217
Hon. Royce C. Lamberth

BRIEF OF DEFENDANTS-APPELLEES IMPAX LABORATORIES, LLC, AND AMNEAL PHARMACEUTICALS, INC.

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February 21, 2023

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1(a) and Circuit Rule 26.1, Impax Laboratories, LLC, and Amneal Pharmaceuticals, Inc., are private, nongovernmental parties in the pharmaceutical industry. Impax Laboratories, LLC, is a wholly owned subsidiary of Amneal Pharmaceuticals, LLC. Amneal Pharmaceuticals, LLC, is owned in part by Amneal Pharmaceuticals, Inc., which is a publicly traded company. The following entities have a 10% or greater ownership interest in Amneal Pharmaceuticals, Inc.'s Class A Shares: Funds affiliated with Fosun International Limited.

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici

The Federal Trade Commission was the plaintiff before the district court and appears as appellant before this Court. Endo Pharmaceuticals Inc., Endo International plc, Impax Laboratories, LLC, and Amneal Pharmaceuticals, Inc. were the defendants before the district court and appear as appellees before this Court.

B. Ruling Under Review

The ruling under review consists of the memorandum opinion and the associated order entered by the district court on March 24, 2022. ECF 74 (under seal) [JA__] and ECF 75 [JA__], respectively. The district court entered a public version of the memorandum opinion on March 30, 2022. ECF 84 [JA__].

C. Related Cases

No related cases are pending before this Court or any other court.

February 21, 2023

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GLOSSARY OF ABBREVIATIONS

Abbreviation	Definition
ANDA	Abbreviated New Drug Application
App.	Brief of Appellant
ECF	ECF entry in the proceedings below, *FTC v. Endo Pharmaceuticals Inc., et al.*, No. 1:21-cv-217 (D.D.C.).
Endo	Endo Pharmaceuticals, Inc., and Endo International plc.
ER	Extended Release
FDA	Food and Drug Administration
FTC	Federal Trade Commission
Impax	Impax Laboratories, LLC, and Amneal Pharmaceuticals, Inc.
JA	Joint Appendix

MATERIAL UNDER SEAL DELETED

INTRODUCTION

The FTC asks this Court to upend patent law, prematurely devalue the patents at issue, and call into question countless other existing patent licenses. That is no exaggeration; it the necessary and intended consequence of the FTC's theory that a patentee must directly compete with its own licensee to drive down prices before the relevant patents expire. Stripped of conclusory rhetoric, all the complaint alleges is that (1) Endo Pharmaceuticals, Inc., holds valid patents covering oxymorphone ER; (2) Endo has licensed its patents to Impax Laboratories, Inc.; (3) Impax has agreed to pay royalties to Endo while it remains [redacted] and (4) Endo remains entitled to use [redacted] its patents to produce oxymorphone ER at any time. That arrangement imposes ***fewer*** restraints on competition than a mine-run exclusive-license agreement, under which a patentee grants the licensee the sole right—against even the patentee itself—to make and sell the invention at supracompetitive prices.

Binding precedent allows exclusive-license arrangements and forecloses any suggestion that a patentee and licensee must compete with each other instead. As this Court explained decades ago, even an "absolutely exclusive license" is "lawful." *U.S. v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1131 (D.C. Cir. 1981). Any other approach would run headlong into the centuries-old rule (and relevant federal statute) that a patent confers not only the monopolist's right to charge

supracompetitive prices, but the prerogative to transfer that right to others who then may act as "exclusive" monopolists too. 35 U.S.C. §261. The FTC's rule would nullify all of this law and history by requiring a patentee-licensor to compete with its licensee. And, applied here, it would negate the monopoly value of Endo's patents, notwithstanding Congress' understanding that Endo—or its licensee—may reap "supracompetitive prices … [as the] legitimate rewards of the patent monopoly." *Studiengesellschaft*, 670 F.2d at 1128-29.

Tellingly, the FTC never disputes that it seeks to limit Endo's rights by commanding internecine sales several years before the patents expire. In fact, such "price competition" is its avowed goal. Appellant's Brief ("App.") at 13, 27. Nor does it seriously attempt to distinguish all the on-point authorities against it.

Instead, the FTC invents from whole cloth the rule that a patentee and its licensee may not change the terms of their license from a non-exclusive license to an (allegedly) exclusive license. That view is flatly incompatible with the settled doctrine that gives parties the freedom to choose between exclusive and non-exclusive licenses, to renounce their preexisting rights to practice patents, and to use a patent to obtain supracompetitive prices for as long as the patent is valid. Unsurprisingly, the FTC does not claim to cite a single case endorsing its position. Rather, it largely relies on analogies to decisions scrutinizing agreements among ***independent*** competitors to pool their ***distinct*** intellectual-property rights to stifle

competition. Those authorities are inapposite to what the FTC alleges here: a patentee and its licensee allocating the benefits of valid and repeatedly-tested patent rights that are owned by a ***single*** patentee. That sort of allocation—whatever anticompetitive effects it supposedly has and regardless of when it occurs—falls squarely within the longstanding approval of "exclusive patent licenses" that "by definition restrain[] trade." *Studiengesellschaft*, 670 F.2d at 1128, 1135; *see also* 35 U.S.C. §261. For this reason alone, affirmance is required.

The FTC's untenable legal premise that a licensee must compete with its patentee, however, is not the only dispositive flaw in the case: the complaint's factual allegations do not plausibly allege ***any*** sort of anticompetitive agreement whatsoever. According to the FTC, when Endo and Impax settled high-stakes litigation in 2017 by compromising on the royalty that Impax allegedly owed Endo for using its patents, that Settlement violated the antitrust laws because it amounted to nothing more than two equally "position[ed] … competitor[s]" entering a "non-compete agreement." App. at 18, 20, 29. That conclusory assertion of anticompetitive conduct is implausible for at least two reasons: (1) Endo and Impax negotiated their arrangement the shadow of a lawsuit that threatened to eliminate Impax's ability to compete at all; and (2) Endo is completely free to begin producing oxymorphone ER at any time. The FTC ignores all of this. Instead, it simply demands that the Court accept the complaint's bare legal conclusions that the 2017

Settlement was adopted with anticompetitive intent, and misrepresents the complaint by claiming that Endo "promised to stay out of the market." *E.g.*, *id.* at 1, 2, 12. But the well-pleaded facts (or lack thereof) undercut any plausible inference of an antitrust violation.

At the end of the day, however, even the FTC's ill-pleaded conclusions are irrelevant as a matter of law. The FTC's overriding legal theory—that a patentee must complete with its own licensee—is incompatible with the settled rule that a patent confers the monopolist's right to use, exclude, and license. It also ignores the specific rights Congress granted Endo, seeking instead to terminate the exclusive powers of the relevant patents years ahead of schedule. And it threatens to impose the exact sort of consumer harms that the FTC purportedly seeks to avoid. After all, if this Court changes the law to impose competition obligations between patentees and licensees, then patentees will be less likely to issue licenses in the first place, thus depriving the public of all potential competition and innovation.

BACKGROUND

I. Endo's Patent Rights

Endo is a pharmaceutical company that develops and manufactures a variety of medications. ECF 3 ¶12 [JA__]. In 2006, Endo began selling Opana ER—the brand name version of oxymorphone ER, which is a long-acting opioid medication. *Id.* ¶¶17-20 [JA__]. At the same time, and as required by federal law, Endo publicly

listed the patents it might assert if another company attempted to manufacture a generic version of Opana ER. *See* 21 U.S.C. §355(b)(1); 21 C.F.R. §314.53.

Since then, Endo's patents related to oxymorphone ER—including several that Endo subsequently acquired—have been repeatedly litigated. One early challenge came from Impax, a pharmaceutical company that focuses on developing, manufacturing, and marketing generic products. ECF 3 ¶16 [JA__]. In 2007, Impax filed an Abbreviated New Drug Application (ANDA) with the FDA for a generic version of Opana ER. *Id.* ¶24 [JA__]. With its ANDA, Impax submitted a "paragraph IV" certification, asserting that Endo's patents were invalid or would not be infringed by its generic product. *Id.* ¶¶25-26 [JA__]; *see also* 21 U.S.C. §355(j)(2)(A)(vii)(IV).

That certification prompted Endo to sue Impax for infringing its patents related to Opana ER. ECF 3 ¶27 [JA__]. After more than two years of litigation, the parties settled during trial in 2010.[1] *Id.* ¶28 [JA__]. In that settlement, Endo granted Impax a license to launch a generic version of the drug in January 2013. *Id.*

[1] Separate litigation over the 2010 Settlement has produced mixed results. The FTC charged that portions of the Settlement unfairly restrained trade, but an administrative law judge ruled in Impax's favor. The FTC reversed, however, and the Fifth Circuit denied Impax's petition for review under a deferential standard. *In re Impax Lab'ys., Inc.*, 2019 WL 1552939 (Mar. 28, 2019); *Impax Lab'ys., Inc. v. FTC*, 994 F.3d 484 (5th Cir. 2021). But more recently, a federal jury returned a full defense verdict in the parallel private antitrust litigation. *See In re Opana ER Antirust Litig.*, No. 14-cv-10150, Dkt. 1002 (N.D. Ill. July 1, 2022).

¶¶28-29 [JA__]. And, to ensure that Impax could continue to sell oxymorphone ER if Endo acquired additional patents, the 2010 Settlement contained a license for after-acquired patents too. *Id.* ¶29 [JA__]; ECF 51-2 §4.1(a) [JA__].[2] However, it also provided that, upon acquisition of new patents, Impax and Endo would "negotiate in good faith an amendment to the terms of the License." ECF 51-2 §4.1(d) [JA__].

Other would-be generic manufacturers took similar steps to launch their own versions of Opana ER. ECF 3 ¶¶32, 34 [JA__]. Endo sued them for patent infringement, and those cases eventually settled on terms that allowed the generic manufacturers to launch their products at various times. *Id.* ¶¶34-37 [JA__]. Unlike the 2010 Settlement with Impax, however, none of the settlements with the other generic manufacturers included a license to any future patents that Endo might acquire. *Id.* ¶¶36-37 [JA__].

Between the 2010 Settlement with Impax and the impending 2013 launch of Impax's generic product, Endo acquired the rights to several additional patents related to Opana ER, including Patents No. 8,309,122 (the '122 patent), No. 8,329,216 (the '216 patent), and No. 8,871,779 (the '779 patent). *Id.* ¶¶44-47 [JA__]. It then asserted its new patents in additional litigation against various manufacturers of generic oxymorphone ER products. *Id.* ¶¶49-56 [JA__]. Unlike

[2] Because the settlements between Impax and Endo are integral to the FTC's claims and their authenticity is not disputed, the Court may consider them on a motion to dismiss. *See Kaempe v. Myers*, 367 F.3d 958, 965 (D.C. Cir. 2004).

the earlier lawsuits, these cases did ***not*** settle, but resulted in final judgments holding that Endo's patents were "not invalid and w[ere] infringed by [various] companies seeking to market generic oxymorphone ER." *Id.* ¶¶50-56 [JA__]; *accord* App. at 1, 9-10, 13 (admitting that "other companies cannot enter the market by virtue of Endo's patents"). Those patents expire over the course of the next decade. ECF 3 ¶¶50, 53 [JA__]; *accord* App. at 13.

II. The Breach of Contract Litigation

Emboldened by its new patents, Endo demanded royalties from Impax too. Although the 2010 Settlement had given a Impax a license to after-acquired patents, *see* ECF 51-2 §4.1 [JA__], Endo pointed to the provision requiring the parties "to negotiate in good faith an amendment to the terms of the License to any patents which issue from any Pending Applications," *id.* §4.1(d) [JA__]; *see also* ECF 3 ¶85 [JA__].

Endo's demands were massive: An 85% royalty on sales of generic oxymorphone ER under the new patents that Endo had acquired. When Impax refused, Endo sued Impax in the District of New Jersey for breach of contract and for infringement of the after-acquired patents. ECF 3 ¶¶85-86; *see also Endo Pharms., Inc. v. Impax Lab'ys, Inc.*, No. 16-cv-2526, Dkt. No. 13 (D.N.J. Aug. 1, 2016). Although Endo's complaint did not immediately seek to enjoin Impax from selling oxymorphone ER, Endo did seek exemplary treble damages for patent

infringement, and it could have eventually sought to prohibit Impax from continuing to sell oxymorphone ER. *See* ECF 3 ¶¶86-87 [JA__]; *accord* 35 U.S.C. §283 (authorizing injunctions "to prevent the violation of any right secured by patent"); *Endo*, No. 16-cv-2526, Dkt. No. 13 at 25 (requesting damages under 35 U.S.C. §284 and seeking "further legal and equitable relief").

Impax moved to dismiss Endo's lawsuit based on the terms of the 2010 Settlement. ECF 3 ¶88 [JA__]; *see Endo v. Impax*, No. 16-cv-2526, Dkt. No. 22 (D.N.J. Aug. 29, 2016). In October 2016, however, the district court denied the motion, ruling that Endo had alleged both breach of contract and patent infringement regarding two patents. ECF 3 ¶89 [JA__]; *see also Endo Pharms., Inc. v. Impax Lab'ys, Inc.*, 2016 WL 6246773, at *4-5 (D.N.J. Oct. 25, 2016). The case thus proceeded to discovery, exposing both parties to considerable litigation expenses and risks.

III. The 2017 Settlement

Endo eventually approached Impax about a settlement. ECF 3 ¶90 [JA__]. After several months of negotiations, in August of 2017 the parties agreed to a framework that embodied a compromise of their conflicting views on royalties. *Id.* ¶¶90, 92 [JA__]. Rather than the 85% royalty that Endo demanded, or the royalty-free license Impax asserted, Impax agreed to pay Endo a royalty equal to [redacted] of Impax's gross profits on sales of its generic oxymorphone ER product. *Id.* ¶94

[JA__]; *see* ECF 52-2 §4(a) [JA__]. Under the 2017 Settlement, that [redacted] royalty is due for as long as [redacted] Endo, however, remains completely free to reenter the market with its own oxymorphone ER product, or to [redacted] ECF 3 ¶¶90, 104 [JA__]. So, far from the FTC's misleading assertion on appeal that "Endo … promised to stay out of the market," App. at 12, the complaint recognizes that [redacted] simply converts Impax's license into a royalty-free license. ECF 3 ¶¶94, 104 [JA__]. In other words, the 2017 Settlement provides a tiered royalty structure to address the possibility that marketplace conditions might change in a way that affects the value of Impax's license.

IV. This Lawsuit

The FTC now challenges the 2017 Settlement under §13(b) of the FTC Act. *See* ECF 3 [JA__]. According to the FTC, the 2017 Settlement is a "restraint of trade" in violation of §1 of the Sherman Act—and thus in violation of the FTC Act—because it amounts to an "agreement[] not to compete" between two competitors. App. at 29 (quoting 15 U.S.C. §1); ECF 3 ¶120 [JA__]. And "for all the [same] reasons," the FTC claims that the 2017 Settlement also violates §2 of the Sherman Act by giving Impax's parent company an unlawful monopoly over "oxymorphone ER products." App. at 47; ECF 3 ¶122 [JA__].

The district court granted Impax's and Endo's motions to dismiss. Although it accepted the FTC's premise that the 2017 Settlement operates "as an exclusive license and non-compete that created a patent monopoly," the court explained that this "anticompetitive activity [was] protected from antitrust scrutiny under the patent laws." ECF 84 at 11-12 [JA__]. After analyzing the 2017 Settlement at length, the court determined Endo's patents created a "valid license and a right to exclude" that conferred a right to charge "supracompetitive prices" "instead of competing." *Id.* at 21 [JA__]. And though the FTC—in an "argument [that was] not easy to parse"—tried to undercut those rights by arguing that Endo and Impax were obliged to compete anyway because Impax had previously acquired a patent license from Endo in 2010, the court rejected that approach on multiple independent grounds. *Id.* at 22 [JA__]. This assertion, the court explained, was not only a bare legal conclusion entitled to "no deference," but ignored that "Endo [had] sued Impax for breach of the 2010 Agreement" that supposedly conferred the operative right. *Id.* [JA__] This assertion was also legally irrelevant, the court reasoned, because "exclusive [patent] licensing agreements" are legitimate even "between parties that c[annot] legally exclude one another." *Id.* [JA__]

SUMMARY OF ARGUMENT

The FTC's rhetoric and accusations cannot cure the legal and factual defects in its case. Binding precedent forecloses the FTC's core legal theory that a patentee

and licensee must compete in practicing the same patents. And the allegations in the complaint—as opposed to the legal conclusions offered on appeal—confirm that the 2017 Settlement was not plausibly anticompetitive in any sense of the word because it secured the rights of ***both*** Endo and Impax to make oxymorphone ER in the shadow of a lawsuit that threatened to drive Impax from the market entirely. Affirmance is required for either reason.

1. The FTC's legal theory reinvents the fundamental relationship between patent and antitrust law. All the FTC purports to allege is that the owner of valid patents that control access to the oxymorphone ER market (Endo) has agreed with a licensee (Impax) that Impax will have the exclusive right to make oxymorphone ER "in exchange" for paying a [redacted] royalty to Endo. App. at 1. That supposed arrangement is no more anticompetitive than a garden-variety "exclusive license," which is both "lawful" under binding precedent and compelled by Congress' recognition that a patent confers an exclusive right to use, make, transfer, or license the invention for supracompetitive returns. *Studiengesellschaft*, 670 F.2d at 1127-28, 1131. In fact, the alleged arrangement here is ***less*** anticompetitive than an exclusive license because, unlike an exclusive license, it admittedly leaves Endo free to enter the market at any time.

To circumvent that settled law and logic, the FTC invents the rule that a patentee and its licensee cannot change the terms of their license from a non-

exclusive license to an allegedly exclusive license. But the FTC cites no authority for that view, relying instead on irrelevant cases involving patent-pooling and price-fixing arrangements. Nor does the FTC explain how its novel rule—which it admits is designed to force price competition between a patent holder and its licensee before the patents expire—is reconcilable with the monopolistic essence of a patent.

2. Setting patent law aside, the FTC has not even plausibly alleged an antitrust violation. If anything, the complaint's allegations and undisputed context show that the 2017 Settlement was pro-competitive. Endo had sued Impax for breach of contract and patent infringement, and its complaint had survived a motion to dismiss. Impax thus faced being driven from the market entirely—either by virtue of Endo's demands for massive royalties and statutory damages, or by Endo's ability to seek an injunction—in which case Endo would be the sole entity able to make oxymorphone ER. Yet Impax managed to settle the case on terms that ***advanced*** competition: Under the Settlement, both Impax and Endo may enter the market at any time—a detail the FTC admitted in its complaint, yet tries to avoid on appeal by claiming that "Endo promised Impax not to compete." *E.g.*, App. at 1, 12. And, under the Settlement, Impax pays Endo only a [redacted] royalty, which is far less than the 85% royalty that Endo demanded at the outset of the case, and which thus provides Endo with a ***greater*** incentive to enter the market. Because the FTC ignores all these realities, it cannot offer a plausible theory for why a Settlement that permits

competition is nonetheless an anticompetitive agreement. It therefore continues to insist on appeal—just as it did in the district court—that this Court must simply adopt its legal conclusion that Impax and Endo were no different than two equally-footed competitors who decided to divide up a market. The well-pleaded facts are to the contrary.

3. Impax agrees with the FTC, however, that the government-action exemption allows this Court to resolve the appeal notwithstanding the bankruptcy proceedings. The exemption applies because this proceeding is brought by a government agency (the FTC) and falls within the agency's police or regulatory power now that the FTC has waived any claim to monetary relief.

STANDARD OF REVIEW

This Court "review[s] *de novo* the District Court's dismissal of the [complaint]." *Kaempe*, 367 F.3d at 963. In doing so, the Court must give the FTC "the benefit of all inferences that can reasonably be drawn from" the "factual allegations." *Id.* But the Court cannot "accept inferences … unsupported by the facts," "legal conclusions cast in the form of factual allegations," or "factual allegations [that] contradict exhibits to the complaint or matters subject to judicial notice." *Id.* (quotations omitted).

ARGUMENT

The FTC's effort to reinvent the law is flawed for at least two reasons. First, even if the Court were to give the FTC the full benefit of its ill-pleaded legal conclusions—that the 2017 Settlement amounts to an anticompetitive agreement giving Impax the exclusive right to make oxymorphone ER free from all competition by Endo—this supposed arrangement would fit comfortably within the Congressionally ordained patent monopoly. Second, the FTC's fundamental theory of an antitrust violation—that Endo and Impax were two competitors who intentionally harmed consumers by executing a "non-compete" agreement—is implausible, given that the 2017 Settlement both resolved significant uncertainty about whether Impax could compete at all and expressly allows Endo to enter the market at any time.

I. Federal Patent Law Authorizes the 2017 Settlement.

The FTC's effort to use the Sherman Act to force a patentee and its licensee to engage in price competition is as meritless as it is revolutionary. And, to be clear, that competition is exactly what the FTC seeks. The FTC does not dispute that Endo holds several patents covering oxymorphone ER. ECF 3 ¶¶50-56 [JA__]. The FTC does not contest the validity of those patents, nor deny that they have repeatedly withstood fully-litigated challenges to their exclusionary power. *Id.* [JA__] And the FTC does not deny that Impax is able to make oxymorphone ER solely because Endo

granted Impax a license to those patents. *Id.* ¶49 [JA__]. Yet rather than allow Impax and Endo to use those valid patents to make and sell oxymorphone ER at whatever prices they deem appropriate until the patents expire, the FTC demands that Impax and Endo engage in "price competition" without further delay. App. at 13, 27. Their supposed "agreement[] not to compete," so the story goes, creates a "restraint of trade" and "monopoly" in violation of the Sherman Act. *Id.* at 29, 46-47.

This theory runs headlong into the reality that the alleged agreement is precisely what patent law authorizes—and what patentees and licensees enter into every day. A patent confers a "monopoly" "to manufacture, use, or sell" the invention. *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 304 U.S. 175, 181 (1938); *accord U.S. v. Gen. Elec. Co.*, 272 U.S. 476, 485, 489 (1926); *Kaempe*, 367 F.3d at 960. This prerogative includes the right to sell or license the invention at "supracompetitive prices," as well as the right to completely "suppress the invention [and] prevent [the public] from using it." *Studiengesellschaft*, 670 F.2d at 1127-28, 1131 (collecting cases); *accord Gen. Elec.*, 272 U.S. at 489-90. And, most relevant here, this prerogative includes the right to grant "an absolutely exclusive license" that excludes all others—including the patentee itself—from using the patent or competing with the licensee. *Studiengesellschaft*, 670 F.2d at 1131; *Rail Trailer Co. v. ACF Indus., Inc.*, 358 F.2d 15, 16-17 (7th Cir. 1966). So, contrary to the FTC's unfounded assertion that it is "strange" for a licensee to "hold[] a monopoly on [the

patentee's] own product" or to pay for that privilege, in reality such a "cash-for-monopoly" exchange is the whole point of an exclusive license. App. at 17, 36.

"The law is settled" on that point: This Court confirmed 40-plus years ago that a patentee may "legally … licens[e] [one party] ***alone*** to use the patent[.]" *Studiengesellschaft*, 670 F.2d at 1131 (emphasis added) (citing *Rail Trailer*, 358 F.2d 15); *accord id.* at 1135. Nor is any other rule plausible in light of Congress' directive that a "patentee … may … grant and convey an exclusive right under his … patent[]." 35 U.S.C. §261. Sure enough, exclusive licenses are "[o]ne of the most common forms of licensing." 2 Roger M. Milgrim & Eric E. Bensen, *Milgrim on Licensing* §15.08 (2020).

These "settled" principles allow the exact arrangement alleged here. *Studiengesellschaft*, 670 F.2d at 1131. If it is permissible for a licensee to agree that it will pay a royalty to the patentee in exchange for the right to exclusively make and sell an invention at "supracompetitive" prices, *id.* at 1127-31, surely Impax could pay Endo a royalty for the right to make and sell oxymorphone ER free from competition by Endo. (Although, as explained below, Endo actually remains free to compete.) The operation of the patent law—and the consequences for consumers—are exactly the same in either case: one drug, produced by one manufacturer, protected by valid patents. That arrangement is precisely what the patent laws contemplate, and therefore "[n]one of the anticompetitive effects" the FTC alleges

"will support a finding that the [2017 Settlement] violate[s]" Sections 1 or 2 of the Sherman Act. *Studiengesellschaft*, 670 F.2d at 1135; *accord id.* at 1126-27; *Gen. Elec.*, 272 U.S. at 485 (rejecting antitrust claim); *Rail Trailer*, 358 F.2d at 16-17 (rejecting Sherman Act claim).

In fact, "[t]he actual licensing arrangement here is ***less*** restrictive than … a lawful exclusive license." *Studiengesellschaft*, 670 F.2d at 1131 (emphasis added). As the complaint admits, the 2017 Settlement "***does not*** explicitly prohibit Endo from competing on its own." ECF 3 ¶104 (emphasis added) [JA__]. Accordingly, the Settlement is not even "a true exclusive patent licensee," because more than "on[e] party [has] the legal right to practice the rights licensed under the patent." *Milgrim on Licensing* §15.08. Rather, the FTC's theory is merely that the 2017 Settlement has the "practical effect" of "eliminat[ing] Endo's financial incentive to [compete]." ECF 3 ¶104 [JA__]. But even giving the FTC full benefit of that inference, a mere "incentive" not to compete cannot possibly violate the Sherman Act given that an "absolutely exclusive license" that expressly bars ***all*** competition from ***all*** quarters is "lawful" in its own right. *Studiengesellschaft*, 670 F.2d at 1131.

A straightforward application of these principles thus disposes of all the FTC's theories of a Sherman Act violation. Even assuming that the FTC is correct that Endo and Impax "agree[d] not to compete," "restrain[ed] trade," "reduced innovation," "monopolized the market for oxymorphone ER," deprived consumers

of the benefits of "competition," and "intended" all of those consequences to boot, App. at 25-31, 46, each and every one of those allegedly "anticompetitive effects … were restraints on what the patent lawfully protects." *Studiengesellschaft*, 670 F.2d at 1128 (dismissing the "four anticompetitive effects found by the district court"); *accord id.* at 1135. Endo's patents, after all, confer a right to charge "supracompetitive" prices. *Id.* at 1128. They confer the right to "suppress the invention" in its entirety. *Id.* at 1127. And they confer the power to bestow the rights and benefits of the patent monopoly on an "exclusive" licensee. *Id.* at 1128-31; *accord Rail Trailer*, 358 F.2d at 16-17 ("a patentee may, without divesting himself of ownership of the patent, grant an exclusive license for the manufacture of the patented device, which license serves to exclude the patentee himself"). There is no merit to the FTC's suggestion that Endo and Impax must ignore these rights, act as competitors, and drive down the value of Endo's patents years before their natural expiration.

A. The FTC Cannot Circumvent the Patent Framework.

The FTC does not openly contest any of this settled doctrine. Instead, it offers a red herring that undergirds each and every argument. According to the FTC, because Impax supposedly had a preexisting right under the 2010 Settlement "to sell oxymorphone ER before it agreed to split the profits with Endo" in the 2017 Settlement, the Court must treat Endo and Impax as two ordinary competitors who

have agreed that one will surrender a contested market to the other to collect monopoly rents. *E.g.*, App. at 2, 18, 31-32, 38, 41.

Setting aside all the factual problems with the FTC's underlying presumption that Impax and Endo were ordinary competitors in 2017, *see* Part II, *infra*,[3] this theory is legally immaterial under basic patent law. The reason is simple. The FTC's allegations are no more anticompetitive than a situation in which a patentee and licensee operating under a non-exclusive patent license (which is "lawful"), decide to convert that license to an exclusive patent license (which is also "lawful"). *Studiengesellschaft*, 670 F.2d at 1127, 1131 ("A patentee may grant one exclusive license ***or*** may grant many licenses" (emphasis added)); *accord Gen. Elec.*, 272 U.S. at 489 (describing various permutations of exclusive and non-exclusive licenses); *Rail Trailer*, 358 F.2d at 17-18 (a patentee may "gran[t] an exclusive license, reserving no right except to collect royalties," and "cut[ting] himself off from practicing the … patent" (quotation omitted)); *Miller Insituform, Inc. v. Insituform of N. Am., Inc.*, 830 F.2d 606, 609 (6th Cir. 1987) ("by terminating the sublicense agreement with the appellant, appellee merely exercised his power to exclude others from using the [patented] process, as was its right under [the patent statute]"). Under the FTC's view, that sort of ordinary decision would be unlawful because it reduces

[3] This argument also ignores the irony of the FTC's efforts in separate litigation to undermine the very 2010 Settlement that allegedly conferred Impax's rights to Endo's patents.

the number of authorized producers from two (the patentee and the licensee) down to one (the licensee). But again, binding precedent is clear that "an absolutely exclusive license"—or even complete "suppress[ion of] the invention" in its entirety—is "lawful." *Studiengesellschaft*, 670 F.2d at 1127, 1131 (collecting cases).

To provide yet another illustration of why the FTC's theory flies in the face of patent law, the allegedly anticompetitive effects here also are no greater than when a patentee and licensee agree to an exclusive license from the outset. To quote the FTC, the patentee in that scenario initially "had a right to sell [the invention]"—by virtue of its patent—but opted to transfer that right exclusively to a licensee and "split the profits." App. at 2; *compare Studiengesellschaft*, 670 F.2d at 1127, 1131 (patentee has right to sell, license, or suppress the invention). In other words, the parties in that scenario ***could*** have competed with each other (by negotiating a non-exclusive license), but instead decided that one of them would be the exclusive producer. Either of those options is fully "lawful" in its own right. *Studiengesellschaft*, 670 F.2d at 1131.

The Seventh Circuit's opinion in *Rail Trailer* further demonstrates why it makes no legal difference whether Impax had a preexisting right to practice the patents. That decision, which this Court invoked in *Studiengesellschaft*, involved "the joint owners of a patent" agreeing that one would have "an exclusive license to manufacture the invention." *Rail Trailer*, 358 F.2d at 16; *see also*

Studiengesellschaft, 670 F.2d at 1131. Such an agreement eliminates competition in no less a manner than the arrangement alleged here, leaving only one party free to practice the patent to the exclusion of all others—***including*** the original patentee. *Rail Trailer*, 358 F.2d at 15, 17-18. Even so, the Seventh Circuit held that a patentee's decision to "grant an exclusive license … which … serves to exclude the patentee himself" is not "an illegal restraint of trade or violation of the anti-trust laws." *Id.* at 16-17. That holding is wholly incompatible with the FTC's fundamental premise that a "pre-existing right [to practice a patent] ***necessarily*** means that [a] later agreement not to compete cannot be characterized as falling within [the] patent-based right to exclude." App. at 2 (emphasis added).

Unsurprisingly, the FTC walks directly into this analysis every time it tries to distinguish it. First, the FTC says that *Rail Trailer* is different because it "involved joint patentees." *Id.* at 34. But a joint patentee has ***greater*** rights to an invention than a mere licensee like Impax (who, in fact, was a disputed licensee being sued for infringement)—and thus by the FTC's own logic a joint patentee's agreement not to compete would cause ***greater*** harms to competition. *Compare* 35 U.S.C. §262 ("each of the joint owners … may make, use, offer to sell, or sell … without the consent of and without accounting to the other"), *and Kaempe*, 367 F.3d at 960 ("Joint owners … are each vested with an undivided share of the patent rights."), *with* ECF 3 ¶29 [JA__] (Endo "owned" and "controlled" the relevant patents and

merely "provided Impax with a license to [them]"). Indeed, given that Endo indisputably retains the right to make [redacted] oxymorphone ER at any time under the 2017 Settlement, the door to competition is open far wider here than in *Rail Trailer*, where the agreement prevented the original joint-patentee from "mak[ing]" or "licens[ing] others to make[] the patented device." 358 F.2d at 15-16.

Second, the FTC tries to distinguish *Rail Trailer* by speculating that the "exclusive license [there] did not adversely affect competition" because "the licensee-owner did not pay to eliminate competition from its joint patentee [but instead] relinquished its right to practice the patent even before it issued." App. at 34. But the FTC's bottom-line premise that the *Rail Trailer* license did not adversely impact competition is once again wrong given that the Seventh Circuit cited the plaintiff's objective of obtaining a "right to make, and to license others to make, the patented device"—in other words, a right to compete. *Rail Trailer*, 358 F.2d at 15-16. The FTC's references to money changing hands and the timing of the agreement are also irrelevant on their own terms, which is why the FTC cites no authority for either point. To the contrary, the Seventh Circuit relied on an earlier Ninth Circuit case that addressed the "grant[of] an exclusive license[] [that] reserv[ed the] right … ***to collect royalties***," meaning that payment of money is immaterial. *Id.* at 17-18 (emphasis added). And the federal statute that allows patentees to "grant and convey an exclusive right" is not only indifferent to whether the recipient pays for the

privilege, but makes clear that the exchange can occur either before ***or*** after the patent issues. 35 U.S.C. §261 (referring in parallel to "[t]he applicant" or the "patentee," and contemplating "subsequent ***purchase[s]***" (emphasis added)).

Third, the FTC suggests that *Rail Trailer* would have come out differently if the Seventh Circuit had found "anticompetitive effects." App. at 34. That is simply untrue. Again, not only did *Rail Trailer* recognize the plaintiff's allegation that it (and others) were excluded from "mak[ing] the patented device," 358 F.2d at 15-16, but it expressly distinguished the specific types of anticompetitive effects that might justify an attack on a patent license. *See, e.g.*, *id.* at 17-18 (contrasting a license that "contained provisions restraining competition on ***other*** products [beyond] the patented devices" (emphasis added)). And, in doing so, it underscored the "uniformly recognized" right to "grant an exclusive license bar[ring the owner] himself from making the invention without running afoul [of] the Sherman Act or the common law." *Id.* at 17.

Finally, and relatedly, the FTC tries to avoid this Court's follow-on decision in *Studiengesellschaft* by completely reinventing what that case held. *See* 670 F.2d at 1131 (relying on *Rail Trailer*). The FTC—correctly—starts by observing that this Court recognized that a patent is not an absolute defense to antitrust scrutiny of certain "anticompetitive effects." App. at 41; *see Studiengesellschaft*, 670 F.2d at 1131-33 (suggesting that such anticompetitive effects might include "tying

arrangements" and certain "price-fixing restrictions"). But then the FTC claims—without citation—that an impermissible anticompetitive effect might include a "license restriction [that] eliminate[s] competition among the licensees that would otherwise have existed." App. at 41. But nothing in *Studiengesellschaft* required that a patentee and licensee compete to produce an invention covered by the same patent. Such a conclusion would have been irreconcilable with the Court's express recognition of the "lawful[ness of an] exclusive license" and of the right of the patentee to "suppress the invention"—both of which have the same (or greater) effect of eliminating potential competition. *Studiengesellschaft*, 670 F.2d at 1127, 1131, 1135. It also would have been incompatible with the Court's recognition that parties can choose between "one exclusive license ***or*** … many licenses." *Id.* at 1127 (emphasis added). And such a conclusion would have been especially perplexing given this Court's invocation of *Rail Trailer*, which approved an agreement that—in the FTC's words—"eliminate[d] competition among [joint-patentees] that would otherwise have existed" given their status as co-owners. App. at 41; *compare Rail Trailer* 358 F.2d at 15-16 (approving the exclusion of the "co-owner" of a patent from "mak[ing] and … licens[ing] others to make[] the patented invention").

B. The FTC's Own Authorities Confirm the Propriety of the 2017 Settlement.

The district court could "f[ind] no cases holding the opposite" of the rule that "exclusive licensing agreements" are legitimate even as "between parties that could

not legally exclude one another." Dkt. 74 at 22. The FTC offers no authorities here, either. Instead, it asks the Court to invert patent law and cast aside precedent based on strained analogies to a handful of cases that allowed antitrust claims to proceed under markedly different circumstances. Each and every one of these decisions only confirms the propriety of the 2017 Settlement.

1. The 2017 Settlement did not involve the consolidation of property rights or price fixing.

The FTC's lead authority is a non-patent case, which did not even consider the intersection of antitrust laws and intellectual-property protections (let alone patent rights). *See Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990). At issue there was an agreement between two "previous[] compet[itors]" in a bar-exam-preparation market—who possessed independent course materials and trade names—to bundle their previously distinct properties so that one competitor could dominate a specific region. *Id.* at 48-49. Here, by contrast, there is ***one*** set of patents (all controlled by Endo), and any right that Impax has to them is derived ***solely*** from Endo. The natural result of that single-source of patent rights is a lawful monopoly which authorizes exclusive licenses. *See Studiengesellschaft*, 670 F.2d at 1127, 1131, 1135; *Rail Trailer*, 358 F.2d at 16-18. In other words, *Palmer*—at most—might imply that independent companies should sometimes pit their freestanding rights against each other, but says nothing about the scope of patent rights or

exclusive patent licenses. And it certainly does not impose a recursive obligation for a patent-licensee to compete with its own licensor.

The FTC's other cases confirm this common-sense point that the patent monopoly—whether held solely by the patentee or conferred on a licensee—does not require self-cannibalism of that monopoly. That is because each decision involved (at minimum) ***independent*** patentees pooling their once-separate rights. In *United States v. Singer Manufacturing Co.*, for example, the Supreme Court held that a group of competitors who owned different patents could not consolidate their separate patents into a single entity to box out other businesses and avoid "fighting each other [over] their ***respective*** patents." 374 U.S. 174, 179, 197 (1963) (emphasis added). The "***aggregating*** [of] ***patents*** in one control," the Court explained, overstepped the "limitations on the concerted activities in which patent ***owners*** may lawfully engage." *Id.* at 194-97 (emphases added and quotation omitted).

So too in *United States v. Line Material Co.*, which involved a "cross-license arrangement" between "two or more patentees in the same patent field" not only to "combine their patents," but to "fix the sale price[s] of the devices" as well. 333 U.S. 287, 288, 305, 312 (1948); *see also id.* at 312-13 & n.24 (discussing prior cases restricting the "pool[ing of] patent licenses" "issued to more than one patentee"). As the Supreme Court stressed, there are profound differences between a patentee exploiting the monopoly of his or her own patents (including through a "licensee"),

and multiple "patentees join[ing] in an agreement … to maintain prices on their several products." *Id.* at 314-15. Could there be any doubt of that interpretation, the Supreme Court has since repeatedly explained—including in *FTC v. Actavis*—that *Line Material* distinguished between "single-patentee practice[s]" and "multiple-patentee agreements," 570 U.S. 136, 150 (2013), and specifically concerned "[a]n arrangement … between patent holders to pool their patents and fix prices," *U.S. v. New Wrinkle, Inc.*, 342 U.S. 371, 380 (1952). This Court, too, has confirmed that *Line Material* involved "***two*** patentees cross-licens[ing] each other's patents" in an arrangement that was more anticompetitive "than [the] mere exploitation of patents." *Studiengesellschaft*, 670 F.2d at 1132 n.14 (emphasis added); *see also Line Material*, 333 U.S. at 308, 311 (leaving intact the rule that the patent "monopoly may be enjoyed exclusively by the patentee" or "license[d to] others [in exchange for] a royalty therefor" in an "agreement … [that] restrains trade"). Here, of course, the parties did not pool their separate patent rights. All the FTC alleges is that Endo and Impax agreed to "exploit[]" patents belonging to Endo alone. *Studiengesellschaft*, 670 F.2d at 1132 n.14.

2. To the extent *Actavis* is relevant, it only confirms the lawfulness of the 2017 Settlement.

It is not entirely clear whether the FTC wishes to avoid or (selectively) invoke *Actavis*, but that equivocation does not matter either way because *Actavis* is irrelevant here. That case said nothing about the lawfulness of exclusive-license

agreements, but instead addressed "reverse payment" settlements in which a patentee pays off a potential infringer in order to avoid a test of a patent's validity under the Hatch-Waxman Act. *Actavis*, 570 U.S. at 141. Regardless, even giving the FTC the benefit of the doubt that *Actavis* is pertinent (as the district court generously did), *Actavis* is wholly consistent with the longstanding rule that patentees and licensees are free to enter into exclusive licenses. Indeed, the FTC does not claim that *Actavis* was anything more than a continuation of this Court's "understanding in *Studiengesellschaft*," App. at 40, which openly endorsed the "lawful[ness] of exclusive license[s]." 670 F.2d at 1131.

a. *Actavis* is irrelevant to this case.

Actavis confronted an "unusual" "kind of settlement agreement [that] is often called a 'reverse payment,'" in which the ***patentee*** induces a potential generic infringer to stay out of the market. 570 U.S. at 141, 147. These reverse-payment settlements arise "specifically in the context of suits brought under [the] statutory provisions" of the Hatch-Waxman Act that "allow[] a generic drug manufacturer … to challenge the validity of a patent owned by an already-approved brand-named drug owner"—a suit that, if successful, grants the generic challenger the "special incentive … [of] a period of 180 days of exclusivity" during which "no other generic can compete." *Id.* at 141-44. To avoid that threat to its patent rights, the brand-name

patentee will sometimes pay the challenger to drop the suit; *i.e.*, "walk[] away with money simply so it will stay away from the patentee's market." *Id.* at 152.

Given "[t]wo special features of Hatch-Waxman," *Actavis* found that certain reverse payments create special risks of anticompetitive harm: First, because "only the first challenger gains the special advantage of 180 days of [exclusivity]," it is unlikely that "[s]ubsequent challengers" will make their own attempts to advance their own generics. *Id.* at 155. Second, the statutory scheme requires a subsequent challenger to wait approximately "30 months before the FDA may approve its application," further quashing any appetite for follow-on litigation over the patent. *Id.* "These features together mean that a reverse payment settlement with the first filer" "removes from consideration the most motivated challenger," and thus effectively deprives the public of a fair test of whether the patent confers a right to exclude in the first place. *Id.* (quotation omitted). "[S]ettlements taking this form" therefore "tend to have significant adverse effects on competition." *Id.* at 147-48.

The 2017 Settlement presents a different situation on every front. Everyone here agrees that "there is no allegation of a reverse payment." ECF 84 at 15, 19 & n.6 [JA__]. All that occurred was a "traditional" settlement where a defendant (Impax) facing serious claims that had survived a motion to dismiss (including Endo's demand for treble damages) managed to reduce its liability and continue selling its product by offering to pay the patentee a [redacted] royalty. ECF 3 ¶¶85-89, 94

[JA__]; *compare Impax*, 994 F.3d at 487 ("Normally, when lawsuits settle the defendant pays the plaintiff."). That is "quite different" from a "reverse payment settlement[]," where "a party with no claim for damages … walks away with money simply so it will stay away from the patentee's market." *Actavis*, 570 U.S. at 152. Moreover, unlike the reverse payments that *Actavis* viewed as ***undermining*** the Hatch-Waxman Act's goal of incentivizing patent challenges, *see* 570 U.S. at 151 (failing to "identify any patent statute" that even "implic[itly]" endorses reverse-payment settlements), the exclusive license alleged here ***promotes*** Congress' decisions to confer patent monopolies and to endorse the "grant[ing] and convey[ing of] exclusive right[s] under … patents." 35 U.S.C. §261; *see also id.* §§154(a)(1) & 271(a). And, of course, *Actavis*' fundamental concern—that a reverse payment would deprive the public of the most effective test of the underlying patent monopoly—is completely absent in this case. *See* 570 U.S. at 151-52 (stressing the policy of "eliminating unwarranted patent grants" and "facilitating challenges to a patent's validity"). As the FTC admits, several actions litigated to final judgment have confirmed the validity of Endo's patents. ECF 3 ¶¶50-56 [JA__].

In other words, this is not a case of a patentee and potential challenger improperly ***preserving*** a patent monopoly by heading off an examination of that monopoly—which by the FTC's own admission was the concern in *Actavis*. *See* App. at 35-36 ("[*Actavis*] held that a patent holder could not avert the risk that its

patent would be declared invalid by sharing its monopoly profits with the challenger to make the threat disappear."). All that Endo and Impax supposedly did was ***allocate*** the benefits of valid patents that have already been exhaustively challenged and upheld in fully litigated lawsuits. That allocation is exactly what federal law protects.

b. Even if *Actavis* were relevant, it would only confirm the lawfulness of the 2017 Settlement.

Although the FTC does not (and cannot) assert that this case involves the sort of reverse payment at issue in *Actavis*, it nonetheless suggests that *Actavis* implicitly endorsed an amorphous and free-roving prohibition on licensing agreements. That dubious approach gets the FTC nowhere either. In the FTC's own telling, its atextual gloss on *Actavis* simply "follow[s] from the Supreme Court's earlier rulings in … *Line Material* … and … *Singer*," as well as from this Court's "[p]resaging" decision in *Studiengesellschaft*. App. at 40. As explained above, however, each and every one of those cases undermines the FTC's novel position. Even by the FTC's own logic, *Actavis* cannot help it reinvent the law.

The FTC's half-hearted efforts to invoke *Actavis* are fatal to its case for another reason. The district court, quite charitably,[4] gave the FTC the full benefit of

[4] The district court ultimately concluded that "the concerns identified in *Actavis* are not present here," ECF 84 at 21 [JA__], thus underscoring the questionable utility of transplanting *Actavis* beyond the Hatch-Waxman reverse-payment context.

the assumption that *Actavis* should inform the analysis, and thus proceeded to draw several "considerations" from *Actavis*—***all*** of which favored Impax. ECF 84 at 14-21 [JA__]. Notably, the FTC fails to contest the district court's analysis of several of these "considerations." *Id.* [JA__][5] And even when the FTC engages with *Actavis* and the district court, each of its arguments only underscores the validity of the 2017 Settlement and the peculiarity of using antitrust law to force a patentee and licensee to compete in practicing the same patents.

First, the FTC disputes that the 2017 Settlement "was an ordinary litigation settlement." App. at 42 (quoting ECF 84 at 20 [JA__]). The Settlement cannot have been "ordinary," the FTC says, because it resolved a "breach of contract suit involv[ing] disputed royalties, and such suits are typically resolved with a compromise on the royalties." *Id.* How perplexing. As the FTC elsewhere admits, Endo initially demanded "that Impax pay an 85% royalty" and sued for treble damages, and the parties ultimately settled the suit—*i.e.*, compromised—by agreeing that "Impax [would] pay Endo [redacted] of the gross oxymorphone ER profits." *Id.* at 11-12. To be sure, as the FTC points out, that middle-ground royalty lasts only while market conditions are such that Impax is the producer of oxymorphone ER.

[5] For example: The FTC does not dispute that Endo's patents are valid. *See* ECF 84 at 15 [JA__]. Nor does the FTC claim that the 2017 Settlement included suspect features such as "a minimum resale price set by multiple patentees cross-licensing patents to each other." *Id.* at 20 (citing *Actavis*, 570 U.S. at 150).

Id. at 42. But there is nothing unusual about offering an "exclusive license" in exchange for royalties. *Studiengesellschaft*, 670 F.2d at 1131; *accord Rail Trailer*, 358 F.2d at 17-18. In fact, exclusive agreements are "[o]ne of the most common forms of licensing." *Milgrim on Licensing* §15.08.[6]

Because there is nothing out of the ordinary about the 2017 Settlement, the FTC is thus left to abandon all limiting principles and argue that even a "commonplace settlement" might be subject to antitrust liability. App. at 42. But far from citing any case involving a similar settlement, all the FTC can muster are passing references to reverse-payment Hatch-Waxman cases where patentees short-circuited challenges brought by putative generic manufacturers, *see King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 402, 406 (3d Cir. 2015) (distinguishing a valid "tender by an infringer of less than the patentee's full demand" to settle a suit, from a patentee's more dubious "induce[ment of] a patent challenger's delay"), and cases that—like *Palmer*—involved parties coordinating the use of "each other's" separate intellectual property, *1-800 Contacts, Inc. v. FTC*, 1 F.4th 102, 111 (2d Cir. 2021). Even then, the FTC's arguments collapse into the

[6] The FTC also never specifies what sort of settlement the parties here (or in future cases) could have reached to avoid antitrust scrutiny. Would a [redacted] royalty be acceptable? A [redacted] royalty? The FTC does not explain. At best, it has at times suggested that the settlement "might" have been legitimate "if it simply set a royalty or conditioned that royalty [redacted]." ECF 58-2 at 28 [JA__]. But that is just another way of insisting that a patentee and licensee must compete—a demand that patent law emphatically rejects.

untenable premise that two parties operating under a single set of valid patent rights must undercut each other as "rivals [instead of] partners." App. at 43. That view clashes with all the case law that "[p]resag[ed] *Actavis*," *id.* at 40—including the "settled [rule] that [a patentee may] legally … license[] [one party] alone to use the patented process," ***even if*** both parties originally had the right to practice the patent. *Studiengesellschaft*, 670 F.2d at 1131; *Rail Trailer*, 358 F.2d at 15-18.

Second, the FTC briefly accuses the district court of "miss[ing] the importance of competitive effects and the purpose underlying a license in its discussion of ... *General Electric*." App. at 44 (citing ECF 84 at 18, 20 [JA__]). But *General Electric* made plain that a patent carries with it the "valuable" prerogatives to grant "exclusive right[s]" and charge supracompetitive "price[s]," 272 U.S. at 489-90, which are the very prerogatives the FTC would destroy by commanding premature "price competition" between a patentee and licensee. App. at 13, 27. And, far from the FTC's bizarre suggestion that *General Electric*'s description of patent rights should be limited to "vertical patent license[s]," *id.* at 44, the law is clear that even joint patentees can decide that only one of them will have the right to practice a patent. *See, e.g.*, *Rail Trailer*, 358 F.2d at 15-16. After all, an "exclusive license"—which is undoubtably "lawful" under binding precedent—operates in a horizontal fashion, as the licensee ***entirely*** supplants the patentee's ability to make and sell the invention. *Studiengesellschaft*, 670 F.2d at 1131. There

is zero basis for the FTC's contrary view that, notwithstanding the well-settled rights conferred by patent law, Impax and Endo nonetheless "[sh]ould have been competitors for sales of the drug." App. at 44.

Third, the FTC claims that the district court "misapplied" *Standard Oil* (as construed in *Actavis*) to hold that an agreement can violate the antitrust laws only if the parties both "dominate the industry and influence the market of unpatented products." App. at 45 (emphasis omitted) (quoting ECF 84 at 20 [JA__]). The district court did no such thing—which is why it considered several other factors, instead of simply beginning and ending its analysis with its observation that the 2017 Settlement affects "no other products" than oxymorphone ER. ECF 84 at 20 [JA__]. Nor can the FTC plausibly contest the correctness of this observation or that it cuts squarely in favor of Impax. As *Standard Oil* explained, there may be reason to scrutinize an arrangement that "curtail[s] the manufacture and supply of an ***unpatented*** product." *Actavis*, 570 U.S. at 150-51 (emphasis added) (quoting *Standard Oil Co. (Ind.) v. U.S.*, 283 U.S. 163, 174 (1931)). But here, there is no suggestion that Endo and Impax did anything regarding "an unpatented product," *id.*—indeed, the FTC never challenges the district court's ruling that "[t]here is no question generic oxymorphone ER infringes on Endo's patents." ECF 84 at 15 [JA__]; *see also* ECF 3 ¶¶50-56 [JA__] (acknowledging failed challenges to the validity of Endo's patents). And though the FTC tries to derive from *Standard Oil*

the highly attenuated negative implication that "oxymorphone ER … is, in effect, unpatented with respect to Impax," App. at 45, that approach once again rests on the misguided view that a licensee has a duty to compete with a patentee. But, more fundamentally, that approach necessarily concedes that oxymorphone ER ***is*** still "[]patented," *id.*—and thus may be "exclusive[ly] license[d]" and sold at the "supracompetitive prices … [which] are legitimate rewards of the patent monopoly." *Studiengesellschaft*, 670 F.2d at 1128-29, 1131; *see also* App. at 1 (admitting that "other companies cannot enter the market by virtue of Endo's patents").

* * *

The FTC's theory would imperil countless exclusive license agreements that are far more restrictive than the 2017 Settlement. It would deprive Endo's patents of their fundamental value—the right to exclude and charge allegedly supracompetitive prices—several years too early. And it would deter all future patent licenses (and the competition and innovation they can bring) for fear that such licenses will impose a requirement of premature, self-destructive competition. It almost goes without saying that settled patent law allows for none of those outcomes. But to the extent it must be said, this Court should simply confirm what precedent already requires.

II. The FTC Does Not Plausibly Allege Any Anticompetitive Conduct Whatsoever.

Patent law would require dismissal regardless of whether the 2017 Settlement had all the "anticompetitive effects" and purposes alleged by the FTC. *Studiengesellschaft*, 670 F.2d at 1128-29, 1135. But the FTC has not even taken the indispensable first step of plausibly alleging an anticompetitive "restraint of trade" or unlawful "monopoly" under §1 or §2 of the Sherman Act. App. at 29, 46. Its theory for both counts is that the 2017 Settlement involved two equally "position[ed] … competitor[s]" entering an "agreement[] not to compete" that "inten[tionally]" "harm[ed] competition" and created an "unlawful[] monopol[y]." *Id.* at 18, 29, 41, 46. But those conclusions are implausible given the allegations in the complaint and the undisputed context of the 2017 Settlement, all of which the Court must consider as a whole. *See, e.g.*, *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 567-68 (2007); *Kaempe*, 367 F.3d at 963 (the Court will not consider "unsupported" inferences, "legal conclusions cast in the form of factual allegations," or allegations that "contradict" reality (quotations omitted)).

To begin, the FTC is far too hasty in its fundamental premise that Impax was a true "competitor" and "rival" of Endo in 2017. App. at 1, 17, 19. Although the FTC frequently offers the legal conclusion that Impax had "an independent right to be in the market" under the "risk-free" license it obtained in 2010, *e.g.*, App. at 1-2, 25, 27-28, 46, the well-pleaded facts instead show that Impax's ability to compete

was in serious doubt. As the district court explained, "Endo [had] sued Impax for breach of the 2010 Agreement," the terms of which required the parties to negotiate modifications if Endo acquired additional patents covering oxymorphone ER. ECF 84 at 22 [JA__]; *accord* ECF 3 ¶86 [JA__]. In that litigation—which came after Endo demanded an 85% royalty from Impax—Endo not only asserted a breach of the 2010 Settlement, but claimed "direct infringement [of the] … [p]atents" and asked for treble damages and "equitable relief." *Endo*, 2016 WL 6246773, at *4-5; *Endo*, No. 16-cv-2526, Dkt. No. 13 at 25 (citing 35 U.S.C. §284); *see also* ECF 3 ¶¶85-86 [JA__]. The suit had also survived a motion to dismiss ruling in which the court cited a ***prior*** decision addressing Endo's patents and finding infringement. *Endo*, 2016 WL 6246773, at *2, 5; *see also* ECF 3 ¶¶ 50, 52 [JA__]. Against this backdrop, Impax's "right to sell oxymorphone ER" in 2017 was far from "risk-free," as the FTC now breezily claims. App. at 2; *see, e.g.*, *Gen. Talking Pictures*, 304 U.S. at 181-82 ("making … sales … outside the scope of [a patent] license … infringe[s] the patents"); *Studiengesellschaft*, 670 F.2d at 1127 (the license is what stands between the licensee and "infringement").

This backdrop also undercuts any plausible suggestion that the 2017 Settlement amounted to an "anticompetitive" agreement or created a monopoly, let alone any inference that Impax intended such consequences. If Endo had prevailed in its suit, the anticompetitive and monopolistic effects ***would have been the same***

or greater than those the FTC wrongly attributes to the 2017 Settlement. Specifically, Endo could have (1) obtained treble damages based on Impax's sales, and (2) retained its ability to exclude all other entrants from the oxymorphone ER market. ECF 3 ¶104 [JA__]; 35 U.S.C. §283. The FTC never explains how that situation is any different than the 2017 Settlement to which it objects. In both cases, Endo is free to "compet[e] on its own," yet ostensibly has a "practical … financial incentive"—payments based on Impax's sales—to leave Impax as the sole producer. *Id.* ¶¶104, 113.

But that is not all. The 2017 Settlement actually ***diminished*** the alleged "incentive" for Endo to eschew competition. Had Endo prevailed in its suit, it could have (among other things) sought to completely enjoin future sales by Impax. *See* 35 U.S.C. §283; *Endo*, No. 16-cv-2526, Dkt. No. 13 at 25 (seeking "equitable relief"). That injunctive power would have allowed Endo, at minimum, to extract the previously-demanded 85% royalty rate from Impax—or to drive Impax from the market altogether, thus leaving Endo as the sole entity capable of producing oxymorphone ER. The Settlement, by contrast, not only allowed Impax to continue manufacturing the medication, but to do so at a ***lower*** royalty rate [redacted] than Endo had demanded (85%). Under the Settlement, Endo therefore has a ***greater*** incentive to exercise its right to enter the market—a right the complaint concedes—as it cannot prevent Impax from selling oxymorphone ER, and it can claim only [redacted] (not an

85%) royalty on those sales. ECF 3 ¶¶94, 104 [JA__]. Yet the FTC completely "ignore[s these] obvious realities about competition," and thus "provide[s] no basis on which a court could determine ***how*** harm to competition result[ed] from the defendants' agreement[.]" *In re McCormick & Co. Pepper Prods. Mkt. & Sales Pracs. Litig.*, 275 F. Supp. 3d 218, 225 (D.D.C. 2017) (quotation omitted) (collecting cases). That defect alone requires dismissal as a matter of law.

Instead, the FTC simply implies—but never clearly states—that Impax was required to fight to the bitter end to (potentially) vindicate its right to a royalty-free license, at which point Endo (theoretically) would have entered the market. This attenuated theory hardly is a suitable basis for a court to actually "determine how harm to competition result[ed] from the [alleged] agreement[.]" *Id.* (emphasis omitted). Regardless, nothing in the antitrust laws required Impax to engage in scorched-earth litigation. "The Sherman Act … does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition." *Verizon Commc'ns Inc. v. Law Offs. of Curtis V. Trinko, LLP,* 540 U.S. 398, 415-16 (2004). Nor does it allow the FTC to send private companies on kamikaze missions to fight the government's battles by proxy. *Id.*; *see also PSKS, Inc. v. Leegin Creative Leather Prods., Inc.*, 615 F.3d 412, 420 (5th Cir. 2010) (affirming dismissal when the supposedly pro-competitive alternative could have led to "wasteful measures" instead of consumer welfare). It

may be that the FTC now believes, with the benefit of highly-selective hindsight, that Impax could have competed with Endo "risk-free" and that Endo should have entered the market as a result. App. at 2. But the facts on the ground render implausible any suggestion that Impax's decision to settle in a way that left both parties free to make oxymorphone ER amounted to nothing more than two competitors intentionally monopolizing the market.

Because the actual facts of the 2017 Settlement are incompatible with the FTC's preferred answer to its own question—"[w]hat are the reasons for the [alleged] restraint?"—the FTC is left to insist that the Court accept its ***legal*** conclusions "that Impax already had a right to sell oxymorphone." App. at 2, 30 (quotation and brackets omitted). The district court rightly rejected that approach, explaining that the FTC's allegation that Endo had no "right to exclude [Impax] is not a factual allegation and receives no deference." ECF 84 at 23 [JA__]. Rather than (belatedly) trying to cure that deficiency, the FTC simply repeats itself, arguing over-and-over that Impax's so-called "right to sell oxymorphone" was actually a "***factual*** allegation[]" that "[t]he district court was required to accept as true." App. at 2 (emphasis added).[7]

[7] *See also, e.g.*, App. at 18 ("[t]he Complaint alleged as fact—which the district court was bound to accept as true—that at the time [of] the 2017 Agreement, Endo's patent did not allow it to exclude Impax"); *id.* at 31 ("the Complaint alleged that Impax had an unequivocal, risk-free license"); *id.* at 33 ("[t]he district

Of course, whether a party has a "right" to do something—let alone the "right" to do something under a contract—is a quintessential legal conclusion that depends on whether the underlying facts (*e.g.*, the contents of the contract and the circumstances of the parties) create such a right. *See Gen. Talking Pictures*, 304 U.S. at 180-81 (explaining that the right to sell patented products depends on "the scope of [the] license"); *Int'l Audiotext Network, Inc. v. Am. Tel. & Tel. Co.*, 62 F.3d 69, 72 (2d Cir. 1995) ("[W]e are not constrained to accept the allegations of the complaint in respect of the construction of the Agreement."); *Lorang v. Alaska S.S. Co.*, 298 F. 547, 549 (W.D. Wash. 1924) (a "[r]ight may be said to be a legal consequence which applies to certain facts"). Otherwise, plaintiffs could always survive a motion to dismiss by claiming that their "rights" were violated as part of a "formulaic recitation of the elements of a cause of action," without any further specification of what facts, details, or circumstances create such rights. *Twombly*, 550 U.S. at 555. But, in reality, "courts are not bound to accept as true a legal conclusion couched as a factual allegation." *Id.* (quotation omitted); *accord Hettinga v. U.S.*, 677 F.3d 471, 476 (D.C. Cir. 2012) ("the Court need not accept inferences drawn by plaintiff if those inferences are not supported by the facts set out in the complaint, nor must the [C]ourt accept legal conclusions cast as factual allegations"); *Kaempe*, 367 F.3d at

court improperly failed to credit the factual allegations that Impax needed no permission in 2017 to sell oxymorphone ER").

963 (similar). They instead must look to the "well-pleaded" facts. *Twombly*, 550 U.S. at 556, 567-68.

Finally, the FTC cannot poison the 2017 Settlement by resorting to propensity evidence from the 2010 Settlement that has been litigated elsewhere with mixed results. *E.g.*, App. at 16-17. This recourse to "historical evidence" as "indicative of a present antitrust violation" is legally improper. *Williamson Oil Co., Inc. v. Philip Morris USA*, 346 F.3d 1287, 1317-18 (11th Cir. 2003) (quotation omitted); *see also id.* at 1316 (refusing to permit "propensity reasoning" that defendants who previously violated the antitrust laws "probably did it again" (quotation omitted)); *cf.* Fed. R. Evid. 404(b). It also omits critical context. At the time of the 2017 Settlement, Endo and Impax were not cozy bedfellows under the 2010 Settlement, but were locked in a bitter lawsuit that had survived a motion to dismiss. And in all events, it ignores the extensive facts undercutting the FTC's claim of historical improprieties—including the ALJ's initial assessment that the 2010 Settlement was valid, as well as a federal jury's recent rejection of a claim that the 2010 Settlement was unreasonably anticompetitive. *See In re Opana ER Antitrust Litig.*, No. 14-cv-10150, Dkt. 1002 (N.D. Ill. July 1, 2022).[8]

[8] As the FTC concedes (both expressly and by otherwise failing to brief the issue), its §2 claim is inadequately alleged for similar reasons. *See* App. at 46-47. A §2 claim requires the plaintiff to prove both (1) the defendant's "possession of monopoly power in the relevant market" and (2) "the willful acquisition or maintenance of that power as distinguished from growth or development as a

III. The Court May Resolve this Appeal Because the FTC Cannot Seek Monetary Relief.

Impax agrees that the Court may decide this appeal despite the pending bankruptcy proceedings. In an ordinary case, those proceedings would require a stay. *See* 11 U.S.C. §362. But this litigation—at least as it currently stands—satisfies both requirements for the government-action exemption. *Id.* §362(b)(4).

First, this FTC lawsuit is "an action or proceeding by a governmental unit." *Id.* Second, this lawsuit is limited to "enforc[ing] [the FTC's] police and regulatory power" because the FTC has waived its claim to any monetary remedy. *Id.* Although litigation may exceed the government's "police and regulatory power" when it seeks "to recover from property of the debtor estate," *In re McMullen*, 386 F.3d 320, 325-27 (1st Cir. 2004), the FTC has renounced any such goal in light of the Supreme

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consequence of a superior product, business acumen or historic accident." *Verizon Comm'ns*, 540 U.S. at 407 (quotation omitted). Impax did not and does not possess "monopoly power," because the 2017 Settlement leaves Endo perfectly free to [redacted] *Id.* Nothing in the complaint—which merely claims that the average price of an oxymorphone ER tablet has fluctuated over the past decade—plausibly alleges that ***Impax*** can control prices. ECF 3 ¶¶111-13 [JA__]. Independently, the complaint also fails to show the "willful acquisition or maintenance of that [alleged] power." *Verizon Comm'ns*, 540 U.S. at 407. Because the bare "opportunity to charge monopoly prices" is perfectly legitimate, "the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive conduct." *Id.* (emphasis omitted). Here, the complaint merely pleads that Impax, when faced with a serious lawsuit that had survived a motion to dismiss, made a reasonable business decision to settle on terms that ***preserved*** its ability to produce oxymorphone ER. That choice—which was far more pro-competitive than an 85% royalty, treble damages, or injunction—is not plausibly unlawful.

Court's recent holding that §13(b) does not "authorize the Commission directly to obtain court-ordered monetary relief." ECF 58-2 at 35-36 [JA__] (quoting *AMG Cap. Mgmt., LLC v. FTC*, 141 S. Ct. 1341, 1347 (2021)).

CONCLUSION

This Court should not invert patent law to require that Endo and Impax undercut each other in practicing the same patents. Such a rule would contradict this Court's own precedent, to say nothing of the established principle that a patent carries with it the monopolist's right to grant an exclusive license. Such a rule would also buck the FTC's supposedly pro-competitive goals by discouraging patentees to grant licenses in the first place. And such a rule would require the Court to credit implausible legal conclusions that allege no anticompetitive conduct whatsoever. For any of the foregoing reasons, this Court should affirm the dismissal of the complaint.

Respectfully submitted,

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February 21, 2023

CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(b) because it contains 11,167 words.

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the typestyle requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point font.

February 21, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on February 21, 2023, (1) the sealed, nonpublic version of this brief was sent to sealedfilings@cadc.uscourts.gov and served on the below counsel of record via email with their consent, and (2) the unsealed, public version of this brief was filed and served via the Court's CM/ECF system:

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